AACC
Advancing
Clinical Laboratory
Science Worldwide

July 22, 2004

Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket #: 2004S-0233

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Department of Health and Human Services (HHS) May 24, 2004 notice requesting comments on how it can it facilitate the development, introduction and dissemination of new medical technologies. We applaud the Department's efforts to address this long-standing problem and the recent creation of a high level, internal medical technology council. AACC believes reducing barriers to new and effective technologies is critical to improving patient care.

Evidence-based Coverage Process

Currently, there are no standard evidence requirements for Medicare and its contractors to make coverage decisions. The federal insurance program and each of its local payers determines on its own what level of evidence is necessary to justify coverage of a test. Unfortunately, this patchwork process requires medical device manufacturers and clinical laboratories to duplicate efforts, seeking local coverage determinations from each of the 46 carriers and fiscal intermediaries. Since each of these contactors has its own process for making these determinations, the result is often inconsistent and conflicting coverage decisions among contractors. A recent study published in the July/August 2004 edition of *Health Affairs* reports less than one-half of local coverage decisions are based on peer-reviewed studies. Instead, most carriers and fiscal intermediaries follow the lead of other contractors.

AACC recommends that CMS develop an evidence-based guidance document for Medicare and its local contractors, which outlines the types and quality of data needed to evaluate and determine coverage for new technologies. The development of such guidance would delineate for device manufacturers and clinical laboratories what data they need to provide for a coverage determination and lead to more consistent and scientifically-based coverage decisions. Further, we suggest that CMS establish a mechanism whereby a test is automatically forwarded for a national coverage decision

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(NCD) once it has been approved by a certain number of contractors, possibly one-third, thus eliminating disparities of coverage, reducing the burden on manufacturers and laboratories pursuing coverage decisions and preserving the local entry option for new technologies.

Appropriately Reimburse New Emerging Technologies

The present system does not have an accurate or efficient means of determining reasonable reimbursement for new technologies, thus Medicare often pays lesser amounts for new assays, which often don't reflect the costs of performing the test. For example, it costs laboratories $276 to conduct an Immunoglobin Gene Rearrangement by PCR, but laboratories only get reimbursed $164 for the test by Medicare. One mechanism available to CMS for addressing this issue is its inherent reasonableness authority, which permits the agency to make payment adjustments on a case-by-case basis. However, this is a lengthy and time consuming process and doesn't address the more global nature of inadequate reimbursement for new technologies. AACC suggests that Medicare establish a process for getting better data from clinical laboratories and medical device manufacturers to make more 'accurate' payment decisions, more clearly define for laboratories the rationale behind denials and provide suggestions for how these denials can be reduced.

A Seamless Process for Making Clearance, Coverage and Payment Decisions

The regulatory process for bringing new technologies to market is disjointed, bureaucratic and, at times, redundant. Currently, it can take a new device 15 months to five years to move through the various governmental and non-governmental processes for approval, coverage and payment. Under the current system, the manufacturer must first go through the FDA review and clearance process, then seek a Medicare coverage determination from CMS or its contractor, get a CPT code from the AMA and finally secure a payment amount. Each stage of the process introduces new decision-makers that may request different types of information to make their decisions. AACC recommends that HHS create a more seamless process, one that streamlines the regulatory process and expedites patient access to potentially life-saving technologies.

One option for addressing this issue is for representatives from the FDA and CMS to meet with device manufacturers prior to developing their study proposals/device submissions so that a more efficient plan of action can be developed in advance. For example, if manufacturers could incorporate the needs of the two agencies into a single study, they could reduce the time needed to generate the required data and get government approval. Another related problem is getting the appropriate CPT code for reimbursement purposes. Currently, Medicare and its contractors only update their billing systems once a year, thus

the AMA only generates new codes annually. Given the advances in information technology, we believe that billing systems can be updated more frequently, possibly quarterly or biannually, to expedite the review and payment processes.

Availability of New CPT codes for New Technology

The current process for obtaining new CPT codes for new clinical laboratory tests is lengthy and tends to discriminate against the creation of method or technology based codes in favor of analyte specific codes. In many cases, multiple technologies are available for measuring the same type of analyte that differ vastly in both cost and clinical utility. When all methods must be reported under the same analyte code, reimbursement could be inadequate for newer methods that may yield superior precision and accuracy or more clinically relevant results. When CPT codes do not provide adequate descriptive precision for complex new technology, CMS should consider creating HCPCS codes that allow more precise ordering and payment.

Inappropriate CCI Edits

Correct Coding Initiative (CCI) edits prevent certain codes from being paid with other codes because they are mutually exclusive or otherwise considered inappropriate coding practice. For example, current CCI edits prevent the submission of a complete CBC with automated WBC differential at the same time as a manual WBC differential, even when the two tests are both ordered and clinically appropriate. In such cases the edit essentially acts as a coverage decision and should be governed by Local or National coverage policy, not a coding edit. One way to improve the quality of CCI edits would be to include them in the existing new laboratory test pricing procedure so that stakeholders could comment and have input when a new code is created. Such a procedure would ensure better quality edits and avoid situations where new technology codes may not be reimbursed because of arbitrary or inappropriate edits.

Provide Greater Funding for EBM-related Technology Studies

The Agency for Healthcare Research and Quality (AHRQ) is the major government agency responsible for funding studies of new technologies and disseminating the results of those studies to health care providers and the general public. AACC recommends that additional resources be allocated to AHRQ so that it can expand its EBM-related activities. The agency's technical assessments are extremely valuable to Medicare and private payers in making coverage decisions and they are invaluable to providers seeking to ascertain the efficacy of new technologies.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics

industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (507) 284-3480, or Vince Stine, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Thomas Moyer, PhD
President
AACC